REMARKS

I. Claim Changes

This application is the U.S. National Stage of PCT/DE 00/00444. The English translation of this German language PCT International Application was originally received in the U.S. Patent Office Mail Room on August 15, 2001, but the application was later accorded a filing date of January 16, 2002. A preliminary amendment was filed October 11, 2001, which added claims 14 to 28 and canceled claims 1 to 13.

The Office Action in the above-identified U.S. Patent Application in the "Office Action Summary" indicates that claims 14 to 28 were examined and rejected. On the other hand, page 2 of the Office Action indicates that claims 1 to 14 (?) were examined. The remainder of this response assumes that claim 14 to 28 were examined and rejected as obvious under 35 U.S.C. 103 (a) over Berggren, et al.

Claims 29 to 45 have been added above and the claims 14 to 28 have been canceled without prejudice. Claims 29 to 45 are substantially the claims as granted by the European Patent Office in the European Patent Application EP 1 152 776 B1, corresponding to PCT/DE 00/00444. This U.S. application is of course the U.S. National Stage of PCT/DE 00/00444.

A patent was granted on European Patent Application EP 1 152 776 B1 on May 22, 2002. A copy of this granted European Patent is being filed together

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with an Information Disclosure Statement. This European Patent contains the same subject matter as the above-identified U.S. Patent Application, since they are part of the same International Application, PCT/DE 00/00444.

II. Rejection of Claims as Obvious over Berggren, et al

Claims 1 to 14(apparently actually 14 to 28) were rejected under 35 U.S.C. 103 (a) as obvious over Berggren, et al.

Berggren, et al, does disclose an injectable composition for delivering a bioactive substance, namely a drug, in a polymeric matrix. The polymeric matrix must be a flowable polymer at a physiologically compatible elevated temperature and a less or non-flowable polymer at or below body temperature (see claim 1). The reason is that the injectable composition is injected into a pocket in the tissue in the mouth at the elevated temperature (and thus it must flow) and then solidifies in the tissue pocket and subsequently delivers the drug.

In preferred embodiments, such as claim 6, the matrix material maybe a polymer of particular hydroxycarboxylic acids, such as lactic acid. Also it may be polyester of hydroxycarboxylic acid. However the chosen polyesters must obey the basic condition regarding flow of claim 1. They must be solid at body temperature, which of course is greater than ambient temperature.

In contrast, applicants disclose polymeric and oligomeric materials built of the chemically similar monomers, but having different properties. In a preferred embodiment the excipients comprise a mixture of liquid low molecular weight oligmers and solid high molecular weight polymeric esters of hydroxycarboxylic

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acids.

This involves two fundamental limitations that distinguish from Berggren, et al. First, Berggren, et al, primarily uses polymeric or oligomeric hydroxy-carboylic acids, not esters of hydroxycarboxylic acids. Applicants are limited to injectable compositions containing a combination of the bioactive ingredient with a mixture of at least two esters of hydroxycarboxylic acids as excipient. According the preferred embodiment of claim 32 one of the esters is a liquid and the other is a solid. As shown in example 11 (which reads on new claim 32) on page 16 of the English translation of the specification 100 mg of solid polymer is mixed with 900 mg of liquid oligomer.

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

> "Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant...Even when obviousness is based on as single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference.." ***In re Kotzab***, 55 U.S.P.Q. 2nd 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141

The reference does not suggest the limitation to the oligomers and polymers of esters of hydroxycarboxylic acid, instead of the poly(hydroxy-

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carboxylic acid). Also the reference discloses a somewhat different mechanism for forming the implant, which would involve oligomers and polymers of somewhat different molecular weights than are used by applicants. The implant of applicants is formed by coagulation of the mixture of excipient oligomers and polymers due to contact with a body fluid, whereas the implant or solid matrix of the reference is formed simply by solidification at the body temperature. The reference composition must function this way because it is inserted in a tissue pocket and is not directly introduced into body fluids, such a saline fluids (column 3, line 65 to 68; column 1, lines 15 to 20; columns 1 and 2 generally).

It is respectfully submitted that none of the new claims 29 to 45 should be rejected under 35 U.S.C. 103 (a) over Berggren, et al.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

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In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

Michael J. Striker,

Attorney for the Applicants

Reg. No. 27,233

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